

Becton, Dickinson and Company (“BD”) as follows:

NATURE OF ACTION

1. Insulet admits that the Complaint purports to state a cause of action for patent infringement. Insulet otherwise denies the allegations of Paragraph 1 of the Complaint, and expressly denies that it has infringed any valid claim of any of the patents asserted in the Complaint.

PARTIES

2. Insulet is without information or knowledge sufficient to form a belief as to the truth of the allegations of Paragraph 2 of the Complaint and, therefore, denies those allegations.

3. Insulet admits the allegations of Paragraph 3 of the Complaint.

JURISDICTION AND VENUE

4. Insulet admits that the Complaint purports to state a cause of action for patent infringement. Insulet otherwise denies the allegations of Paragraph 4 of the Complaint, and expressly denies that it has infringed any valid claim of any of the patents asserted in the Complaint.

5. Insulet admits this Court has subject matter jurisdiction over claims of patent infringement under 28 U.S.C. §§ 1331 and 1338(a).

6. Insulet admits that it sells a product known as the Omnipod® Insulin Management System. Insulet otherwise denies the allegations of Paragraph 6 of the Complaint.

7. Insulet denies the allegations of Paragraph 7 of the Complaint.

8. Insulet denies the allegations of Paragraph 8 of the Complaint.

9. Insulet denies the allegations of Paragraph 9 of the Complaint.

10. Insulet admits the allegations of Paragraph 10 of the Complaint.

11. Insulet admits the allegations of Paragraph 11 of the Complaint.

COUNT 1: PATENT INFRINGEMENT OF U.S. PATENT NO. 5,536,249 C1

12. Insulet repeats, realleges, and incorporates by reference, its responses to the allegations of Paragraphs 1-11 of the Complaint as if fully set forth herein.

13. Insulet denies the allegations of Paragraph 13 of the Complaint, except that it admits that: (a) a copy of U.S. Patent No. 5,536,249 C1 (the “’249 patent”), entitled “Pen-Type Injector with a Microprocessor and Blood Characteristic Monitor,” is attached to the Complaint as Exhibit A; (b) the parties identified on the face of the ’249 patent as the inventors are Thomas P. Castellano and Robert Schumacher; (c) the ’249 patent states that it issued on July 16, 1996 and that Visionary Medical Products, Inc. was the assignee of the patent at the time of its issuance; and (d) the copy of the ’249 patent that is attached to the Complaint as Exhibit A includes an Ex Parte Reexamination Certificate that has the same title, lists the same inventors of the ’249 patent, and has an issue date of October 9, 2007. Insulet is without information or knowledge sufficient to form a belief as to the truth of the allegations that BD is the current assignee and owner of the ’249 patent, and, therefore, denies those allegations.

14. Insulet denies the allegations of Paragraph 14 of the Complaint.

15. Insulet admits that it does not have a license or permission to use the ’249 patent, but denies that it requires a license or permission to use the ’249 patent.

16. Insulet denies the allegations of Paragraph 16 of the Complaint.

17. Insulet denies the allegations of Paragraph 17 of the Complaint.

18. Insulet denies the allegations of Paragraph 18, except it admits that it has received letters from BD dated September 22, 2009, February 12, 2010, and April 27, 2010, which letters speak for themselves.

19. Insulet denies the allegations of Paragraph 19 of the Complaint.

COUNT 2: PATENT INFRINGEMENT OF U.S. PATENT NO. 5,925,021

20. Insulet repeats, realleges, and incorporates by reference, its responses to the allegations of Paragraphs 1-11 of the Complaint as if fully set forth herein.

21. Insulet denies the allegations of Paragraph 21 of the Complaint, except that it admits that: (a) a copy of U.S. Patent No. 5,925,021 (the “’021 patent”), entitled “Medication Delivery Device with a Microprocessor and Characteristic Monitor,” is attached to the Complaint as Exhibit B; (b) the persons identified on the face of the ’021 patent as the inventors are Thomas P. Castellano and Robert Schumacher; and (c) the ’021 patent states that it issued on July 20, 1999 and that Visionary Medical Products, Inc. was the assignee at the time of issuance. Insulet is without information or knowledge sufficient to form a belief as to the truth of the allegations that BD is the current assignee and owner of the ’021 patent, and, therefore, denies those allegations.

22. Insulet denies the allegations of Paragraph 22 of the Complaint.

23. Insulet admits that it does not have a license or permission to use the ’021 patent, but denies that it requires a license or permission to use the ’021 patent.

24. Insulet denies the allegations of Paragraph 24 of the Complaint.

25. Insulet denies the allegations of Paragraph 25 of the Complaint.

COUNT 3: PATENT INFRINGEMENT OF U.S. PATENT NO. 5,957,895

26. Insulet repeats, realleges, and incorporates by reference, its responses to the allegations of Paragraphs 1-11 of the Complaint as if fully set forth herein.

27. Insulet denies the allegations of Paragraph 27 of the Complaint, except that it admits that: (a) a copy of U.S. Patent No. 5,957,895 (the “’895 patent”), entitled “Low-Profile Automatic Injection Device with Self-Emptying Reservoir,” is attached to the Complaint as Exhibit C; (b) the persons identified on the face of the ’895 patent as the inventors are Burton H.

Sage and Robert I. Connelly; and (c) the '895 patent states that it issued on September 28, 1999 and that BD was the assignee of the patent at the time of its issuance. Insulet is without information or knowledge sufficient to form a belief as to the truth of the allegation that BD is the current assignee and owner of the '895 patent, and, therefore, denies that allegation.

28. Insulet denies the allegations of Paragraph 28 of the Complaint.

29. Insulet admits that it does not have a license or permission to use the '895 patent, but denies that it requires a license or permission to use the '895 patent.

30. Insulet denies the allegations of Paragraph 30 of the Complaint.

31. Insulet denies the allegations of Paragraph 31 of the Complaint.

AFFIRMATIVE DEFENSES

First Affirmative Defense

The Complaint fails to state a claim upon which relief can be granted.

Second Affirmative Defense

Insulet's products do not infringe, and Insulet has neither induced nor contributed to the infringement of, any of U.S. Patent Nos. 5,536,249 C1, 5,925,021 or 5,957,895.

Third Affirmative Defense

The claims of each of U.S. Patent Nos. 5,536,249 C1, 5,925,021 and 5,957,895 are invalid because they fail to satisfy the conditions for patentability stated in Title 35 of the United States Code, including, among other sections, §§ 101, 102, 103, and 112.

Fourth Affirmative Defense

BD's claim for damages is limited by 35 U.S.C. § 287(a).

Fifth Affirmative Defense

BD's claim for injunctive relief is barred because it has an adequate remedy at law, it is not being, and is not in danger of being, irreparably injured, the balance of the hardships is not in its favor, and the public interest is not served by the granting of injunctive relief.

Sixth Affirmative Defense

BD's claims are barred by laches.

Seventh Affirmative Defense

BD's claims are barred by the doctrine of estoppel.

Additional Defenses

Insulet reserves the right to assert additional defenses that may become known to it through discovery.

PRAYER FOR RELIEF

Insulet respectfully requests that the Court:

(a) Enter judgment that Insulet has not infringed, induced the infringement of, or contributed to the infringement of, any claim of any of U.S. Patent Nos. 5,536,249 C1, 5,925,021 or 5,957,895;

(b) Enter judgment that each of the claims of U.S. Patent Nos. 5,536,249 C1, 5,925,021 or 5,957,895 is invalid;

(c) Enter judgment denying BD all of the relief requested in the Complaint and dismissing BD's claims with prejudice;

(d) Enter judgment that this is an exceptional case within the meaning of 35 U.S.C. § 285 and awarding Insulet its costs and attorneys' fees; and

(e) Grant Insulet such other and further relief as the Court deems just in the circumstances.

COUNTERCLAIMS

Insulet asserts the following Counterclaims against BD:

PARTIES

1. Counter-claimant Insulet Corporation is a Delaware corporation with a principal place of business in Bedford, Massachusetts.

2. Counter-defendant Becton, Dickinson and Company (“BD”) alleges that it is a New Jersey corporation with a principal place of business at 1 Becton Drive, Franklin Lakes, New Jersey.

JURISDICTION AND VENUE

3. These Counterclaims arise under the patent laws of the United States, as enacted under Title 35 of the United States Code and the provisions of the Declaratory Judgment Act, 28 U.S.C. §§ 2201-2202. This Court has subject matter jurisdiction over these Counterclaims pursuant to 28 U.S.C. §§ 1331-1338 because these Counterclaims arise under the patent laws of the United States, and pursuant to 28 U.S.C. §§ 2201-2202 because an actual controversy exists between Insulet and BD.

4. These Counterclaims arise out of the same transaction or occurrence that is the subject of BD’s Complaint. This Court has personal jurisdiction over BD because it submitted itself to the jurisdiction of this Court by filing its Complaint in this judicial district. The acts committed by BD that are the basis of this declaratory judgment action occurred in this judicial district.

5. In its Complaint, counterclaim-defendant BD alleges that Insulet has infringed, induced the infringement of, and contributed to the infringement of, United States Patent Nos. 5,536,249 C1, 5,925,021 or 5,957,895. Because Insulet denies that it infringes, or that it has

infringed or induced, or contributed to, the infringement of, any valid claim of any of those patents, an actual and justiciable controversy has arisen and now exists between Insulet, on the one hand, and BD, on the other, as to whether Insulet infringes any claim of any of those patents and as to whether claims of those patents are valid.

6. Venue is proper in this judicial district pursuant to 28 U.S.C. § 1391 because a substantial part of the events that give rise to these Counterclaims occurred in this district.

**COUNT I: DECLARATORY JUDGMENT REGARDING
NON-INFRINGEMENT OF U.S. PATENT NO. 5,536,249 C1**

7. Insulet repeats, realleges, and incorporates by reference, the allegations of Paragraphs 1-6 of these Counterclaims as if fully set forth herein.

8. Insulet does not infringe, has not infringed, does not and has not induced the infringement of, and does not and has not contributed to the infringement of, U.S. Patent No. 5,536,249 C1.

**COUNT II: DECLARATORY JUDGMENT REGARDING
NON-INFRINGEMENT OF U.S. PATENT NO. 5,925,021**

9. Insulet repeats, realleges, and incorporates by reference, the allegations of Paragraphs 1-6 of these Counterclaims as if fully set forth herein.

10. Insulet does not infringe, has not infringed, does not and has not induced the infringement of, and does not and has not contributed to the infringement of, U.S. Patent No. 5,925,021.

**COUNT III: DECLARATORY JUDGMENT REGARDING
NON-INFRINGEMENT OF U.S. PATENT NO. 5,957,895**

11. Insulet repeats, realleges, and incorporates by reference, the allegations of Paragraphs 1-6 of these Counterclaims as if fully set forth herein.

12. Insulet does not infringe, has not infringed, does not and has not induced the infringement of, and does not and has not contributed to the infringement of, U.S. Patent No. 5,957,895.

COUNT IV: DECLARATORY JUDGMENT
REGARDING INVALIDITY OF U.S. PATENT NO. 5,536,249 C1

13. Insulet repeats, realleges, and incorporates by reference, the allegations of Paragraphs 1-6 of these Counterclaims as if fully set forth herein.

14. The claims of U.S. Patent No. 5,536,249 C1 are invalid because they fail to satisfy the conditions for patentability specified in 35 U.S.C. § 101.

15. The claims of U.S. Patent No. 5,536,249 C1 are invalid because they fail to satisfy the conditions for patentability specified in 35 U.S.C. § 102.

16. The claims of U.S. Patent No. 5,536,249 C1 are invalid because they fail to satisfy the conditions for patentability specified in 35 U.S.C. § 103.

17. The claims of U.S. Patent No. 5,536,249 C1 are invalid because they fail to satisfy the conditions for patentability specified in 35 U.S.C. § 112.

COUNT V: DECLARATORY JUDGMENT
REGARDING INVALIDITY OF U.S. PATENT NO. 5,925,021

18. Insulet repeats, realleges, and incorporates by reference, the allegations of Paragraphs 1-6 of these Counterclaims as if fully set forth herein.

19. The claims of U.S. Patent No. 5,925,021 are invalid because they fail to satisfy the conditions for patentability specified in 35 U.S.C. § 101.

20. The claims of U.S. Patent No. 5,925,021 are invalid because they fail to satisfy the conditions for patentability specified in 35 U.S.C. § 102.

21. The claims of U.S. Patent No. 5,925,021 are invalid because they fail to satisfy the conditions for patentability specified in 35 U.S.C. § 103.

22. The claims of U.S. Patent No. 5,925,021 are invalid because they fail to satisfy the conditions for patentability specified in 35 U.S.C. § 112.

COUNT VI: DECLARATORY JUDGMENT
REGARDING INVALIDITY OF U.S. PATENT NO. 5,957,895

23. Insulet repeats, realleges, and incorporates by reference, the allegations of Paragraphs 1-6 of these Counterclaims as if fully set forth herein.

24. The claims of U.S. Patent No. 5,957,895 are invalid because they fail to satisfy the conditions for patentability specified in 35 U.S.C. § 101.

25. The claims of U.S. Patent No. 5,957,895 are invalid because they fail to satisfy the conditions for patentability specified in 35 U.S.C. § 102.

26. The claims of U.S. Patent No. 5,957,895 are invalid because they fail to satisfy the conditions for patentability specified in 35 U.S.C. § 103.

27. The claims of U.S. Patent No. 5,957,895 are invalid because they fail to satisfy the conditions for patentability specified in 35 U.S.C. § 112.

REQUEST FOR RELIEF

Insulet respectfully requests that the Court grant the following relief:

(a) Declare and enter judgment that Insulet does not infringe, has not infringed, does not induce the infringement of, has not induced the infringement of, and does not contribute to the infringement of, and has not contributed to the infringement of, any claim of any of United States Patent Nos. 5,536,249 C1, 5,925,021 or 5,957,895;

(b) Declare and enter judgment that each of the claims of United States Patent Nos. 5,536,249 C1, 5,925,021 and 5,957,895 is invalid;

(c) Enter judgment determining that this case is an exceptional case within the meaning of 35 U.S.C. § 285, and award Insulet its costs and attorneys' fees; and

(d) Grant Insulet such other and further relief as the Court deems just in the circumstances.

DEMAND FOR JURY TRIAL

Insulet hereby demands a trial by jury of all issues so triable by a jury in this action.

Respectfully submitted,

INSULET CORPORATION,

By its attorneys,

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CERTIFICATE OF SERVICE

I, Ronald A. Giller, hereby certify that this document filed through the ECF System will be sent electronically to the registered participants as identified on the Notice of Electronic Filing and paper copies will be emailed to those indicated as non-registered participants on January 6, 2011.

/s/ Ronald A. Giller
Ronald A. Giller